JUL 21 2004

EXHIBIT # 1

510(K) SUMMARY

This summary of 5l0(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA l990 and 21 CFR §807.92.

The assigned 5l0(k) number is: K041411

1. Submitter's Identification:

Microlife Intellectual Property GmbH, Switzerland
Max Schmidheiny-Strasse 201
9435 Heerbrugg / Switzerland

Date Summary Prepared: May 26, 2004

Contact: Mr. Gerhard Frick

2. Name of the Device:

Microlife Blood Pressure Monitor, Model BP3BT0-AP

3. Predicate Device Information:

The Microlife Upper Arm Automatic Blood Pressure Monitor, Model BP-3BTO-AP is substantially equivalent to the Microlife Automatic Blood Pressure Monitor, Model BP-3BT0-1, K# 013485, and, the A&D Medical Lifesource Blood Pressure Monitor, Model UA-787V, K#012472.

4. Device Description:

The Microlife Upper Arm Automatic Blood Pressure Monitor, Model BP-3BTO-AP is designed to measure the systolic and diastolic blood pressure and pulse rate of an individual by using a non-invasive technique in which an inflatable cuff is wrapped around the Upper arm. Our method to define systolic and diastolic pressure is similar to the auscultatory method but uses an electronic capacitive pressure sensor rather than a stethoscope and mercury manometer. The sensor converts tiny alterations in cuff pressure to electrical signals, by analyzing those signals to define the systolic and diastolic blood pressure and calculating pulse rate, which is a well - known technique in the market called the "oscillometric method".

5. Intended Use:

The Microlife Upper Arm Blood Pressure Monitor, Model BP-3BT0-AP, is a device intended to measure the systolic and diastolic blood pressure and pulse rate of an adult individual by using a non-invasive technique in which an inflatable cuff is wrapped around the upper arm.

The device detects the appearance of irregular heartbeat during measurement, and gives a warning signal with the reading once the irregular heartbeat is detected.

6. Comparison to Predicate Devices:

Both the subject device and Microlife predicate use the well known oscillometric method within the software algorithm to determine the systolic and diastolic blood pressure and pulse rate. Both devices use a similar capacitance-type pressure sensor to translate the pressure variations to electrical signals that can be interpreted by an integrating circuit. For both devices, the software is capable of a split slope resolution to improve accuracy over the entire range. The subject device differs from the Microlife predicate in the irregular heartbeat detection function.

Both the subject device and the A&D Medical Lifesource predicate have the same indications for use. Both devices include an irregular heartbeat detection function. Both the subject device and the A&D Medical Lifesource predicate use the well known oscillometric method within the software algorithm to determine the systolic and diastolic blood pressure and pulse rate.

7. Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:

Testing information demonstrating safety and effectiveness of the Microlife Automatic Blood Pressure Monitor, Model BP3BT0-AP in the intended environment of use is supported by testing that was conducted in accordance with the FDA November 1993 Draft "Reviewer Guidance for Premarket Notification Submissions", DCRND, which outlines Electrical, Mechanical and Environmental Performance Requirements.

The following testing was conducted:

a. General Functions Test

b. Reliability Test - Operation Conditions
c. Reliability Test - Drop Testing
d. Reliability Test - Storage
e. Reliability Test - Vibrating Testing
f. EMC Test
g. IEC 60601-1 Safety Test

None of the testing demonstrated any design characteristics that violated the requirements of the Reviewer Guidance or resulted in any safety hazards. It was our conclusion that the Microlife Automatic Blood Pressure Monitor, Model BP-3BT0-AP tested met all relevant requirements of the aforementioned tests.

8. Discussion of Clinical Tests Performed:

Since the blood pressure measuring algorithm in this device is exactly the same as in the predicate device, BP3BT0-1, no clinical validation for blood pressure measurement is required. Instead, we conducted a simulator comparison study for the function of irregular heartbeat detection.

9. Conclusions:

We have demonstrated that the Microlife Automatic Blood Pressure Monitor, Model BP3BT0-AP, is as safe and effective as the predicate, the Microlife Automatic Blood Pressure Monitor, Model BP-3BT0-1, and, the A&D Medical Lifesource, based on electrical, mechanical and environmental testing results as well as the FDA DCRND November 1993 Draft "Reviewer Guidance for Premarket Notification Submissions", and, the ANSI/AAMI Voluntary Standard, SP10-1992 testing results.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 21 2004

Microlife Intellectual Property GmbH
c/o Ms. Susan D. Goldstein-Falk
mdi Consultants, Inc.
55 Northern Blvd., Suite 200
Great Neck, NY 11021

Re: K041411
Trade Name: Microlife Upper Arm Blood Pressure Monitor, Model BP-3BT0-AP
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: II (two)
Product Code: DXN
Dated: May 26, 2004
Received: May 27, 2004

Dear Ms. Goldstein-Falk:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4648. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Exhibit B

510(k) Number (if known): K041411

Device Name: Microlife Upper Arm Blood Pressure Monitor, Model BP-3BT0-AP

Indications For Use:

The Microlife Upper Arm Blood Pressure Monitor, Model BP 3BT0-AP, is a device intended to measure the systolic and diastolic blood pressure and pulse rate of an adult individual by using a non-invasive technique in which an inflatable cuff is wrapped around the upper arm.

The device detects the appearance of irregular heartbeat during measurement, and gives a warning signal with the reading once the irregular heartbeat is detected.

Prescription Use ___ **OR** **Over-The Counter Use** X
(Per 21 CFR 801 Subpart D) **(21 CFT 807 Subpart C)**

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K041411

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)